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\*Admitted only in Maryland  
\*Admitted only in Virginia  
\*Practice Limited to  
Federal Agencies

October 28, 2004

Commissioner for Patents  
PO Box 1450  
Alexandria, VA 22313-1450

**Mail Stop: Amendment**

**WRITER'S DIRECT NUMBER:**  
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**INTERNET ADDRESS:**  
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Re: U.S. Utility Patent Application  
Appl. No.: 10/728,766; Filed: December 8, 2003  
For: **Methods for Production of Proteins**  
Inventors: Deb K. CHATTERJEE *et al.*  
Our Ref: 0942.4200002/RWE/AWL

Sir:

Transmitted herewith for appropriate action are the following documents:

1. Information Disclosure Statement;
2. A listing of the cited documents on Form PTO-1449 (15 pages);
3. Copies of the cited documents (AR1-AT1, AR2-AT2, AR3-AT3, AR4, AS4, AR5-AT5, AR6-AT6, AR7, AS7, AR8, AS8, AR9, AT9, AR10-AT10, AT11, AR12-AT12, AR13-AT13, AR14, AT14, AR15 and AS15); and
4. One (1) return postcard.

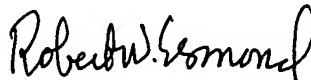
It is respectfully requested that the attached postcard be stamped with the date of filing of these documents, and that it be returned to our courier. In the event that extensions of time are necessary to prevent abandonment of this patent application, then such extensions of time are hereby petitioned.

Commissioner for Patents  
October 28, 2004  
Page 2

The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 19-0036.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.



Robert W. Esmond  
Attorney for Applicants  
Registration No. 32,893

RWE/AWL:ddc  
Enclosures

327863\_1.DOC



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

Deb K. CHATTERJEE *et al.*

Appl. No.: 10/728,766

Filed: December 8, 2003

For: **Methods for Production of Proteins**

Confirmation No.: 9843

Art Unit: 1652

Examiner: To Be Assigned

Atty. Docket: 0942.4200002/RWE/AWL

**Information Disclosure Statement**

Commissioner for Patents  
PO Box 1450  
Alexandria, VA 22313-1450

Sir:

Listed on accompanying Form PTO-1449 are documents that may be considered material to the examination of this application, in compliance with the duty of disclosure requirements of 37 C.F.R. §§ 1.56, 1.97 and 1.98.

Copies of documents **AA1-AK1, AA2-AF2, AL1-AN1, AT4, AT7, AT8, AS9, AR11, AS11 and AS14** were cited by or submitted to the Office in an IDS that complies with 37 C.F.R. § 1.98(a)-(c) in Application No. 09/004,068, Chatterjee *et al.*, filed January 8, 1998, which is relied upon for an earlier filing date under 35 U.S.C. § 120. Thus, copies of these documents are not attached. 37 C.F.R. § 1.98(d). A copy of each additional document is provided.

Applicants reserve the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered.

Where the publication date of a listed document does not provide a month of publication, the year of publication of the listed document is sufficiently earlier than the effective U.S. filing date and any foreign priority date so that the month of publication is not in issue. Applicants have listed publication dates on the attached Form PTO-1449 based on information presently available to the undersigned. However, the listed publication dates should not be construed as an admission that the information was actually published on the date indicated.

This statement should not be construed as a representation that a search has been made, or that information more material to the examination of the present patent application does not exist. The Examiner is specifically requested not to rely solely on the material submitted herewith.

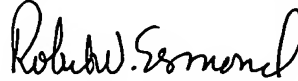
This Information Disclosure Statement is being filed before the mailing date of a first Office Action on the merits. No statement or fee is required.

It is respectfully requested that the Examiner initial and return a copy of the enclosed Form PTO-1449, and indicate in the official file wrapper of this patent application that the documents have been considered.

The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 19-0036.

Respectfully submitted,

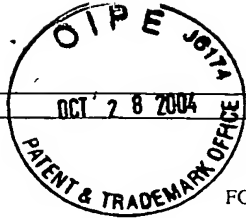
STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.



Robert W. Esmond  
Attorney for Applicants  
Registration No. 32,893

Date: October 28, 2004

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OCT 28 2004

FORM PTO-1449

## INFORMATION DISCLOSURE STATEMENT

Page 1 of 15

ATTY. DOCKET No.  
0942.4200002/RWE/AWLAPPLICATION No.  
10/728,766APPLICANT(S)  
Chatterjee *et al.*FILING DATE  
December 8, 2003ART UNIT  
1652

## U.S. PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB-CLASS	FILING DATE
	AAI	4,405,720	09/20/1983	Merril			01/18/1982
	AB1	4,468,466	08/28/1984	Morrissey			02/16/1982
	AC1	4,507,233	03/26/1985	Saito <i>et al.</i>			04/18/1983
	AD1	4,575,452	03/11/1986	Lee <i>et al.</i>			09/21/1984
	AE1	4,677,196	06/30/1987	Rausch <i>et al.</i>			09/06/1985
	AF1	4,766,224	08/23/1988	Rausch			08/19/1985
	AG1	4,782,027	11/01/1988	Lee <i>et al.</i>			01/22/1987
	AH1	4,920,059	04/24/1990	Moeremans <i>et al.</i>			06/12/1985
	AI1	5,132,439	07/21/1992	Shultz <i>et al.</i>			11/19/1990
	AJ1	5,273,906	12/28/1993	Shultz <i>et al.</i>			07/20/1992
	AK1	5,279,792	01/18/1994	Moeremans <i>et al.</i>			06/03/1991

## FOREIGN PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
	AL1	WO 92/01707	02/06/1992	WIPO			Yes No
	AM1	WO 96/17942	06/13/1996	WIPO			Yes No
	AN1	WO 97/28248	08/07/1997	WIPO			Yes No
	AO						Yes No
	AP						Yes No

## OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	1	Allen, R.C., and Budowle, B., "Component Visualization," in <i>Gel Electrophoresis of Proteins and Nucleic Acids</i> , Walter De Gruyter, Berlin, Germany, pp. 204-272 (1994)
	AS	1	Ausubel, F.M., <i>et al.</i> , "Protein Expression," in <i>Current Protocols in Molecular Biology</i> , Vol. 2, John Wiley & Sons, Inc., Hoboken, NJ, pp. 16.4.1-16.8.14 (1994)
	AT	1	Barger, B.O., <i>et al.</i> , "Estimation of Molecular Weight by Polyacrylamide Gel Electrophoresis Using Heat Stable Fluorophors," <i>Anal. Biochem</i> , 70:327-335, Academic Press (1976)

EXAMINER	DATE CONSIDERED
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EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

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EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB-CLASS	FILING DATE
	AA2	5,292,646	03/08/1994	McCoy <i>et al.</i>			07/28/1992
	AB2	5,330,902	07/19/1994	Keck <i>et al.</i>			01/15/1993
	AC2	5,449,758	09/12/1995	Hartley			12/02/1993
	AD2	5,605,691	02/25/1997	Carroll			09/29/1993
	AE2	5,616,502	04/01/1997	Haugland <i>et al.</i>			05/19/1995
	AF2	5,705,649	01/06/1998	Shultz <i>et al.</i>			11/09/1995
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**FOREIGN PATENT DOCUMENTS**

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	AL						Yes No
	AM						Yes No
	AN						Yes No
	AO						Yes No
	AP						Yes No

**OTHER (Including Author, Title, Date, Pertinent Pages, etc.)**

	AR	<u>2</u>	Betton, J-M., and Hofnung, M., "Folding of a Mutant Maltose-binding Protein of <i>Escherichia coli</i> Which Forms Inclusion Bodies," <i>J. Biol. Chem.</i> 271:8046-8052, American Society for Biochemistry and Molecular Biology (1996)
	AS	<u>2</u>	BIORAD, "Electrophoresis and Blotting Standards. Protein Standards," <i>Life Science Research Products, Price List S</i> , p. 316, (1993)
	AT	<u>2</u>	Bosshard, H.F., and Datyner, A., "The Use of a New Reactive Dye for Quantitation of Prestained Proteins on Polyacrylamide Gels," <i>Anal. Biochem.</i> 82:327-333, Academic Press (1977)

EXAMINER	DATE CONSIDERED
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	AL						Yes No
	AM						Yes No
	AP						Yes No
	AO						Yes No
	AP						Yes No

**OTHER (Including Author, Title, Date, Pertinent Pages, etc.)**

	AR	<u>3</u>	Buchner, J., and Rudolph, R., "Renaturation, Purification and Characterization of Recombinant F <sub>ab</sub> -Fragments Produced in <i>Escherichia coli</i> ," <i>Biotechnology</i> 9:157-162, Nature Pub. Co. (1991)
	AS	<u>3</u>	Carter, P., "Site-Specific Proteolysis of Fusion Proteins," in <i>Protein Purification: From Molecular Mechanisms to Large-Scale Processes, American Chemical Society Symposium Series, Vol. 427</i> , Ladisch, M.R., <i>et al.</i> , eds., American Chemical Society, Washington, DC, pp. 181-193 (1990)
	AT	<u>3</u>	Chatterjee, D.K., <i>et al.</i> , "Cloning and overexpression of the gene encoding bacteriophage T5 DNA polymerase," <i>Gene</i> 97:13-19, Elsevier Science (1991)

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	AN						Yes No
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	AP						Yes No

**OTHER (Including Author, Title, Date, Pertinent Pages, etc.)**

	AR	<u>4</u>	Chatterjee, D.K., <i>et al.</i> , "Genetic organization of the <i>Kpn1</i> restriction-modification system," <i>Nucl. Acids Res.</i> 19:6505-6509, Oxford University Press (1991)
	AS	<u>4</u>	Coburn, G.A., and Mackie, G.A., "Overexpression, Purification, and Properties of <i>Escherichia coli</i> Ribonuclease II," <i>J. Biol. Chem.</i> 271:1048-1053, American Society for Biochemistry and Molecular Biology (1996)
✓	AT	<u>4</u>	Dalmia, B.K., <i>et al.</i> , "Domain E of <i>Bacillus macerans</i> Cyclodextrin Glucanotransferase: An Independent Starch-Binding Domain," <i>Biotechnol. Bioeng.</i> 47:575-584, Wiley Interscience (1995)

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	AN						Yes No
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	AP						Yes No

**OTHER (Including Author, Title, Date, Pertinent Pages, etc.)**

	AR	<u>5</u>	Datyrner, A., and Finnimore, E.D., "A Prestaining Method for the Quantitative Assay of Proteins on Polyacrylamide Gels," <i>Anal. Biochem.</i> 55:479-491, Academic Press (1973)
	AS	<u>5</u>	Dekker, N., <i>et al.</i> , "In vitro folding of <i>Escherichia coli</i> outer-membrane phospholipase A," <i>Eur. J. Biochem.</i> 232:214-219, Blackwell Science (1995)
	AT	<u>5</u>	Derman, A.I., and Beckwith, J., " <i>Escherichia coli</i> Alkaline Phosphatase Localized to the Cytoplasm Slowly Acquires Enzymatic Activity in Cells Whose Growth Has Been Suspended: a Caution for Gene Fusion Studies," <i>J. Bacteriol.</i> 177:3764-3770, American Society for Microbiology (1995)

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	AP						Yes
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**OTHER (Including Author, Title, Date, Pertinent Pages, etc.)**

	AR	<u>6</u>	Flynn, E., <i>et al.</i> , "Protein Analysis with the BenchMark™ Protein Ladders," <i>Focus</i> 19:33-35, Life Technologies (1997)
	AS	<u>6</u>	Georgiou, G., <i>et al.</i> , "Localization of Inclusion Bodies in <i>Escherichia coli</i> Overproducing $\beta$ -Lactamase or Alkaline Phosphatase," <i>Appl. Environ. Microbiol.</i> 52:1157-1161, American Society for Microbiology (1986)
	AT	<u>6</u>	Griffith, I.P., "Immediate Visualization of Proteins in Dodecyl Sulfate-Polyacrylamide Gels by Prestaining with Remazol Dyes," <i>Anal. Biochem.</i> 46:402-412, Academic Press (1972)

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	AN						Yes No
	AO						Yes No
	AP						Yes No

## OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	7	Haugland, R, "Handbook of Fluorescent Probes and Research Chemicals. Section 1.5, Dyes with Absorption Maxima Between 500 and 540 nm," pp. 25-29, Molecular Probes Inc., available at: <a href="http://web.archive.org/web/19970607210142/www.probes.com/acrobat/ch01-5.pdf">http://web.archive.org/web/19970607210142/www.probes.com/acrobat/ch01-5.pdf</a>
	AS	7	Haugland, R, "Handbook of Fluorescent Probes and Research Chemicals. Section 1.6, Long-Wavelength Dyes," pp. 29-35, Molecular Probes Inc., available at: <a href="http://web.archive.org/web/19970607210142/www.probes.com/acrobat/ch01-6.pdf">http://web.archive.org/web/19970607210142/www.probes.com/acrobat/ch01-6.pdf</a>
	AT	7	Hitomi, Y., <i>et al.</i> , "High Efficiency Prokaryotic Expression and Purification of a Portion of the Hepatitis C Core Protein and Analysis of the Immune Response to Recombinant Protein in BALB/c Mice," <i>Viral Immunol.</i> 8:109-119, Mary Ann Liebert Inc. (1995)

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	AP						Yes
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## OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	<u>8</u>	Hochuli, E., and Piesecki, S., "Interaction of Hexahistidine Fusion Proteins with Nitrilotriacetic Acid-Chelated Ni <sup>2+</sup> Ions," <i>METHODS: A Companion to Methods in Enzymology</i> 4:68-72, Academic Press (1992)
	AS	<u>8</u>	Höög, J-O., <i>et al.</i> , "Nucleotide sequence of the thioredoxin gene from <i>Escherichia coli</i> ," <i>Biosci. Rep.</i> 4:917-923, The Biochemical Society (1984)
	AT	<u>8</u>	Kim, S-O., and Lee, Y.I., "High-level expression and simple purification of recombinant human insulin-like growth factor I," <i>J. Biotechnol</i> 48:97-105, Elsevier Science (1996)

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	AN						Yes No
	AO						Yes No
	AP						Yes No

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	AR	2	Kuhelj, R., <i>et al.</i> , "The preparation of catalytically active human cathepsin B from its precursor expressed in <i>Escherichia coli</i> in the form of inclusion bodies," <i>Eur. J. Biochem.</i> 229:533-539, Blackwell Science (1995)
✕	AS	2	LaVallie, E.R., <i>et al.</i> , "A Thioredoxin Gene Fusion Expression System That Circumvents Inclusion Body Formation in the <i>E. coli</i> Cytoplasm," <i>Biotechnology</i> 11:187-193, Nature Pub. Co. (1993)
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